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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,828	05/08/2006	Per Wollmer	613-101	1945

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,828	WOLLMER ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/28/2007&01/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Applicant's amendment filed on 11/28/2007 and Information Disclosure Statement filed on 11/28/2007 have been received and entered into the application. Accordingly claims 19 and 27 are amended. The pending claims are 19-33 and are presented for examination.

Information Disclosure Statement

2. The Information Disclosure Statement filed on 01/30/2008 and 11/28/2007 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Response to Arguments

3. Applicant's arguments filed on 11/28/2007 with respect to claims under 35 U.S.C. 103(a) have been fully considered but they are not persuasive. Rejections and/or objections not reiterated from previous office action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. The 103(a) rejections are maintained and made **FINAL**.

4. With respect to claim 33, a topographical error was noticed. In the previous office action mailed on 06/14/2007, it was described in Baker disclosure (see page 7, lines 4-8) the method of administering the composition as oral, nasal, buccal, rectal vaginal, topical or nasal sprays or in any other form effective to deliver active composition to a site of microorganism infection which meets the claim limitation.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims because the specification, while being enabling for treating certain allergies caused by airborne particles using the microemulsion as claimed, does not reasonably provide enablement for preventing all the possible allergies caused by airborne particles using a composition of microemulsion as claimed.

Attention is directed to Inre Wands, 8 USPQ 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 court recited eight factors as set forth in the previous office action.

Applicants assert that the instant application is a method to prevent allergic rhinitis and it does not claim to treat allergic rhinitis.

According to applicant argument statement, there are no symptoms to treat allergic rhinitis at this stage, and thus at what stage applicants are preventing allergic rhinitis or how applicants will be capable of preventing allergic rhinitis

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,506,803) in view of Wright (US 5,618,840).

Baker discloses an emulsion composition for decreasing the infectively morbidity, and rate of mortality associated with a variety of pathogenic organisms. The emulsion comprising about 5 to 50% aqueous phase, 30-90% of oil phase and 3-15% of surfactant. The aqueous phase comprises water at a pH of about 4 to10, preferably about 6 to 8. The oil phase comprises 5-10 vol. % of an organic solvent such as alcohols (see column 10, lines 50-68). The surfactant comprises a non-ionic surfactant such as polysorbate detergents sold under the trademarks Tween 80 (see column 11

lines 30-33). And also emulsion comprises glycerol mono oleate in the initial oil phase (see column 15, lines 13-15). The emulsions can be formulated into sprays and lotions by including suitable carrier such as fatty acids, polyethylene glycols, and like (see column 14, lines 10-15). And further, the emulsion composition suitable for administration to oral, nasal, buccal, rectal, vaginal, topical or nasal sprays or in any other form effective to deliver active compositions to a site of microorganism infection (see column 23, lines 28-35).

Baker meets the claim limitations but fails to disclose explicitly specific amounts of monoacyl glycerol component in the emulsion. However, the oil-in-water emulsion comprising monoacyl glycerol is well known in the art as shown by Wright.

Wright discloses an antibacterial oil-in-water emulsion comprising droplets of an oily phase such as soybean oil, sesame oil, fish oil and like, and mono glycerol ester selected from group consisting of glycerol mono oleate and glycerol monostearate. The emulsions can be administered to individuals, for example, orally to treat or prevent Helicobacter pylori infection (see abstract).

It would have been obvious to one of ordinary skill in the art to modify the emulsion composition disclosed by Baker to include monoacyl glycerol compounds as pharmaceutically acceptable carrier because Wright teaches that the incorporation of the glycerol monooleate as effective antibacterial activity to inhibit the growth of bacteria, subsequent invasion and dissemination of the infectious pathogen may be prevented. And also the antibacterial emulsions can be used, for example, in pharmaceutical applications to mucous membranes, oral surfaces, skin, inner ear

surfaces, or the surfaces of any bodily orifice, such as vagina or rectum. One of ordinary skill in the art would have been motivated to include monoacyl glycerol derivative such as glycerol monooleate in the composition advanced by Baker. Based on the teaching of Wright, there is reasonable expectation that the glycerol monooleate containing emulsions would be highly desirable non-toxic emulsions and also suitable for administration to peripheral membrane linings of the nose, the eyes, the ears, of a mammal. Thus, one would have been motivated to employee glycerol monooleate to make a combination to have additive effects and enhance the pharmaceutical applicability.

It is noted that the intended use" a mouth or nasal spray device and a filter device containing the microemulsion composition" recited in the claims 28-30 is considered, but the claim is properly included in this rejection because a recitation of the intended use of claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. However, Baker discloses emulsion composition that can be formulated into sprays, syringable composition in containers (e.g., injection or blow molded plastic containers into which desired vials are retained). If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant's arguments filed on 11/28/2007 have been fully considered but they are not persuasive.

Applicant asserts that there is not teaching in Baker which would cause the skilled person to make the reversed phase emulsions (water-in-oil) and also does not address the allergic rhinitis.

This is not found persuasive because, firstly claims are generic to emulsion compositions and it does not state or recite whether the emulsion is water-in-oil or oil-in-water type. And secondly, regarding Baker does not address the allergic rhinitis, it is noted that claims 19-30 and 33 do not recite the allergic rhinitis.

4. Claims 31-32 are rejected under35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,506,803) and Wright (US 5,618,840) in view of Chilton et al. (US 2002/0188024).

With respect to claims 31-32, Baker and Wright meets the limitations as described above but fails to include method of preventing allergic rhinitis (hay fever) in emulsion composition.

However, Chilton discloses an oil-in-water-emulsion comprising borage oil and marine oil, at least one emulsifying agent or emulsion stabilizer, water and polyunsaturated fatty acids for treatment of an inflammatory disorder. More particularly, compositions and methods for controlling or reducing symptoms of inflammation or inflammatory conditions that include the use of unsaturated fatty acids, and/or unsaturated fatty acid analogs. And further, the emulsion may also be used in the treatment of conditions including asthma, allergic rhinitis, allergic rhinoconjunctivitis for example (see para 0020 and 0028).

It would have been obvious to one of ordinary skill in the art to modify the emulsion composition disclosed by Baker and Wright and using the composition for treatment of symptoms/preventing allergic rhinitis. Subjects consuming the oral emulsion show enhanced bioavailability of polyunsaturated fatty acid for treatment of inflammatory disorders. One of ordinary skill in the art would have been motivated to incorporate the teaching of Chilton in the composition advanced by Baker and Wright. Based on the teaching of Chilton, there is reasonable expectation that the polyunsaturated fatty acid containing emulsion would be providing a means in the art to treat the same function of preventing allergic rhinitis. It has been held that the combination of two or more compositions each of which is taught in the prior art to be useful for the same purpose flows logically. In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980); In re Susi, 169 USPQ 423, 426 (1971); In re Crockett, 126 USPQ 186, 188 (1960).

Applicant asserts that Chilton is silent on the prevention of allergic rhinitis, and thus cannot cause the skilled worker to modify the teaching of Baker and Wright.

This is not found persuasive because Chilton disclose treatment of symptoms of inflammatory disorders caused due to asthma, allergic rhinitis allergic rhinoconjunctis and the like. Treatment of symptoms may lead to preventing either at early stage or at later stage which eventually may stop the inflammatory infections.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER